by the manufacturers with their comments sheds little light on the role of nicotine in cigarettes and does not significantly change the evidence in the record.

The Agency's discussion of the evidence of the manufacturers' statements, research, and actions is divided into several parts. In section II.C.2., the Agency discusses the statements and research of each of the major cigarette companies and the Council for Tobacco Research, a trade association to which they belong. This evidence shows that the manufacturers have known for decades that nicotine has the characteristics of addictive drugs and causes other significant pharmacological effects and that consumers use cigarettes primarily to obtain the pharmacological effects of nicotine, including satisfaction of their addiction. This evidence also shows that in internal discussions, senior researchers for the cigarette manufacturers refer to cigarettes as drug delivery systems, calling them a "dispenser for a dose unit of nicotine,"[410] a vehicle for delivery of nicotine,"[411] and other similar terms. This evidence is sufficient by itself to establish that cigarettes are intended to affect the structure and function of the body, because it shows that the manufacturers "have in mind" that their products will be used specifically for pharmacological purposes.

In sections II.C.3. and II.C.4., the Agency discusses the second basis for determining the manufacturers' intent through their statements, research, and actions—namely, the evidence that manufacturers have "designed" cigarettes to provide pharmacologically active doses of nicotine to consumers. In section II.C.3., the Agency discusses the product research and development activities of the manufacturers. This

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[410] Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 5. *See* AR (Vol. 12 Ref. 133).

[411] Teague CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on The Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 1. *See* AR (Vol. 531 Ref. 125).

evidence shows that the manufacturers have conducted extensive product research and development to establish the dose of nicotine necessary to produce pharmacological effects and to optimize the delivery of nicotine to consumers.

In section II.C.4., the Agency discusses the evidence that the manufacturers do in fact manipulate and control nicotine deliveries in their commercial cigarettes. This evidence supports a finding that the manufacturers manipulate and control the delivery of nicotine in commercial cigarettes to provide a pharmacologically active dose of nicotine to consumers. Taken together, the evidence in sections II.C.3. and II.C.4. establishes yet another basis for finding that cigarettes are intended to affect the structure and function of the body.

In section II.C.5., the Agency concludes that, when considered cumulatively, the evidence from the statements, research, and actions of the manufacturers is internally consistent and mutually corroborating, further supporting the finding that the effects of cigarettes on the structure and function of the body are "intended" by the manufacturers. Finally, in section II.C.6., the Agency responds to substantive comments concerning the evidence of the manufacturers' statements, research, and actions that are not addressed in sections II.C.2. to II.C.5.[412]

[412] The discussion of the statements, research, and actions of the manufacturers in this section cites hundreds of documents. It is the totality of the evidence from these documents that the Agency relies upon. No single document cited by the Agency is essential to the Agency's conclusion in section II.C. that the manufacturers intend their products to affect the structure and function of the body. In particular, although considerable evidence of the statements, research, and actions of the manufacturers was submitted to the Agency after the publication of the Jurisdictional Analysis on August 11, 1995, none of this evidence is essential to the Agency's finding of intended use in section II.C. The new evidence is summarized below because it provides persuasive corroboration that the cigarette manufacturers do intend to affect the structure and function of the body. However, the Agency would reach the same conclusions regarding the intent of the manufacturers even without this additional evidence. In addition, none of the documents in the Agency's docket of confidential documents is essential to the Agency's determination. *See* AR (Vol. 505-518).

1. "Intended Use" May Be Established on the Basis of the Statements, Actions, and Research of the Manufacturers

Reliance on the statements, research, and actions of manufacturers to establish intended use is consistent with the plain language of the statute. The statute provides that products "intended" to affect the structure or any function of the body are drugs or devices. Sections 201(g)(1)(C) and 201(h)(3). According to a canon of statutory construction, words used by Congress, unless otherwise defined, will be interpreted as taking their ordinary meaning. *See, e.g., Smith v. United States*, 508 U.S. 223, 228 (1993); *Chevron v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 860 (1984). In this case, the ordinary meaning of "intend" includes "to have in mind" and "to design" for a particular use. These plain meanings allow the Agency to consider the manufacturer's statements, research, and actions in determining intended use.

The *American Heritage Dictionary,* for instance, defines "intend" as: "1. To have in mind; plan. 2.a. To design for a specific purpose. b. To have in mind for a particular use. . . ."[413] Consistent with this meaning, the Agency interprets "intended" uses to include those specific uses that are "in the mind" of the manufacturer or for which the manufacturer "designs" the product. The plain meaning of the statute thus permits the Agency to inquire into the statements, research, and actions of the manufacturer. What the manufacturer says in internal documents, the kind of research the manufacturer conducts, and the actions of the manufacturer in producing its product can all be evidence

[413] *The American Heritage Dictionary of the English Language,* 2d ed. (Boston: Houghton Mifflin Co., 1991), 668. *See* AR (Vol. 526 Ref. 95, vol. V). Other dictionary definitions are similar. *See, e.g., Webster's New World Dictionary of American English,* 3d college ed. (New York: Simon & Schuster, Inc., 1988), 702 ("intend 1. *to have in mind as a purpose*; plan 2. to mean (something) to be *or be used (for); design. . . .*") (emphasis added).

of the particular uses the manufacturer has in mind or for which the manufacturer has designed the product.

FDA's regulations on the meaning of "intended uses" are consistent with the statutory language and explicitly contemplate that FDA may examine the knowledge, actions, and expressions of manufacturers and other vendors. 21 CFR 201.128 and 801.4. These regulations state that intended uses are to be established on the basis of "objective intent." FDA's "objective intent" standard means that the Agency may consider objective evidence to determine a manufacturer's intent, notwithstanding the manufacturer's assertions that pharmacological effects and uses are not intended. As the courts have recognized, "FDA is not bound by the manufacturer's subjective claims of intent but *can find actual therapeutic intent on the basis of objective evidence.*" *NNFA v. Mathews*, 557 F.2d at 334 (emphasis added); *accord United States v. Storage Spaces Designated Nos. "8" and "49,"* 777 F.2d 1363, 1366 n. 5 (9th Cir. 1985) ("self-serving labels cannot be used to mask true intent"), *cert. denied*, 479 U.S. 1086 (1987).

The regulations recognize that as a fact finder, FDA may consider a broad range of evidence of intended use, including evidence of the statements, research, and actions of the manufacturer. For example, the regulations state that "the objective intent is determined by such persons' *expressions . . . or oral or written statements.*" 21 CFR 201.128 (emphasis added). These "expressions" and "oral or written statements" can include relevant and probative intracompany memoranda or research.

Indeed, the regulations provide express authority for FDA to consider evidence of the manufacturer's actual intent. The regulations state that "objective intent . . . may be shown by the circumstances that the article is, *with the knowledge of [the manufacturer],*

offered and used for a purpose for which it is neither labeled nor advertised." *Id.* (emphasis added). The regulations also direct FDA to consider circumstances in which the manufacturer "*knows*, or *has knowledge of facts* that would give him notice" that a product is to be used for purposes other than those expressly promoted by the manufacturer. *Id.* (emphasis added). Proving whether a manufacturer "knows" or has "knowledge of facts that would give him notice" of pharmacological uses of a product can include an inquiry into the actual understanding of the manufacturer, including consideration of the statements, research, and actions that may be probative of the manufacturer's actual knowledge.

Moreover, the regulations provide that objective intent may be shown by the "*circumstances surrounding the distribution of the article.*" *Id.* (emphasis added). This broad phrase allows the fact finder to infer the intended uses of a product based on, among other factors, the conduct of the manufacturer that occurs prior to distribution. For example, evidence that shows how distributed tobacco products are designed and formulated is reasonably considered a "circumstance surrounding distribution of the article."

Courts have also recognized that the Agency may consider "objective evidence" to determine a manufacturer's intent. *See NNFA v. Mathews*, 557 F.2d at 334; *United States v. Storage Spaces*, 777 F.2d at 1366; *Latex Surgeons' Gloves*, 799 F. Supp. at 1295 (circumstances surrounding manufacture and distribution of product demonstrated intended use despite manufacturer's claim to FDA that product was not a device); *Hanson*, 417 F. Supp. at 35 (statements by plaintiff distributors and importers that drug was needed by patients to treat cancer is relevant to intended use).

The Agency's role in determining intended use on the basis of the statements, research, and actions of the manufacturer is that of a fact finder. The Agency's responsibility is to reach the best factual judgments it can from the record of the statements, research, and actions before it, including evidence submitted during the comment period.

2. The Cigarette Manufacturers Understand That Nicotine Has Addictive and Other Pharmacological Effects and That Smokers Use Cigarettes To Obtain These Effects

As discussed below, the evidence in the record shows that the cigarette manufacturers have extensive knowledge of effects of nicotine on smokers. The manufacturers know that nicotine has the characteristics of other addictive drugs; that it provides other significant pharmacological effects; and that it is the primary reason that smokers use cigarettes. This evidence establishes that when the manufacturers offer cigarettes to the public, they "have in mind" that their cigarettes will be used by smokers to obtain the pharmacological effects of nicotine. This evidence is thus sufficient by itself to establish that the manufacturers intend the pharmacological uses of their products.

a. The Statements and Research of Philip Morris

The administrative record includes over three decades of internal statements and research on nicotine by Philip Morris, the nation's largest cigarette manufacturer. These documents indicate that senior researchers and officials at Philip Morris have long viewed nicotine as a "powerful pharmacological agent"[414] and "the primary reason"[415] people

[414] Charles JL (Philip Morris Inc.), *Nicotine Receptor Program-University of Rochester* (Mar. 18, 1980), in 141 Cong. Rec. H7680 (daily ed. Jul. 25, 1995). *See* AR (Vol. 14 Ref. 175a).

[415] Philip Morris Inc., Draft Report Regarding a Proposal for a "Safer" Cigarette, Code-named *Table*, at 1. *See* AR (Vol. 531 Ref. 122).

smoke. This knowledge shows that Philip Morris understands that its product will affect the structure and function of the body and will be used by consumers for these drug effects.

i. The Views of Senior Researchers and Officials. Philip Morris officials recognized the importance of the pharmacological effects of nicotine in cigarettes as early as 1961. That year, Helmut Wakeham, a senior Philip Morris research scientist, informed the company's research and development committee that "nicotine is believed essential to cigarette acceptability."[416] Wakeham also explained the pharmacological effects of nicotine, stating that "low nicotine doses stimulate, but high doses depress functions" and that nicotine contributes to the "pleasurable reactions or tranquillity" produced by smoking.[417]

By 1969, the views of the Philip Morris scientists on the pharmacological effects of cigarettes were communicated to the Philip Morris board of directors. During that year, Wakeham, who was then vice president for research and development, briefed the Philip Morris board of directors on why people smoke. He expressed his department's "conviction" that "the ultimate explanation for the perpetuated cigaret habit resides in the pharmacological effect of smoke upon the body of the smoker." He further stated that smokers' craving for cigarettes is so strong that "the cigaret will even preempt food in times of scarcity":

Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 6. *See* AR (Vol. 638 Ref. 2).

[416] Wakeham H (Philip Morris Inc.), *Tobacco and Health—R&D Approach* (Nov. 15, 1961), at 43. *See* AR (Vol. 125 Ref. 1314).

[417] *Id.* at 40.

> [T]he psychosocial motive is not enough to explain continued smoking. Some other motive force takes over to make smoking rewarding in its own right. Long after adolescent preoccupation with self-image has subsided, the cigaret will even preempt food in times of scarcity on the smoker's priority list. . . . The question is "Why?"
>
> . . . .We are of the conviction, . . . that the ultimate explanation for the perpetuated cigaret habit resides in the pharmacological effect of smoke upon the body of the smoker, the effect being most rewarding to the individual under stress.[418]

Wakeham's views on the central importance of the "pharmacological effect" of nicotine were shared by other senior researchers and officials at Philip Morris, as the following examples demonstrate:

- In 1972, Philip Morris scientist William Dunn characterized cigarettes as a nicotine delivery system in the following language:

> Think of the cigarette pack as a storage container for a day's supply of nicotine. . . .
>
> *Think of the cigarette as a dispenser for a dose unit of nicotine. . . .*
>
> Think of a puff of smoke as the vehicle of nicotine . . . .
>
> *Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke.*[419]

- In 1974, Philip Morris' director of research, Thomas Osdene, who subsequently became vice president for science and technology, approved and sent to Wakeham and other senior Philip Morris officials a report that analogized smoking to drug use. The report's "working hypothesis" is that "[d]ose-control continues even after the puff of smoke is drawn into the mouth." The report postulates that the consumer regulates

[418] Wakeham H (Philip Morris Inc.), *Smoker Psychology Research*, presented to Philip Morris board of directors (Nov. 26, 1969), at 237, 240. *See* AR (Vol. 11 Ref. 142).

[419] Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 5-6 (emphasis added). *See* AR (Vol. 12 Ref. 133).

smoke intake "to achieve his habitual quota of the pharmacological action," and notes that if smokers deprived of cigarettes display an increase in aggression, it may be explained as "the emergence of reactions . . . not unlike those to be observed upon withdrawal from any of a number of habituating pharmacological agents."[420]

- In 1976, Philip Morris researcher A. Udow wrote a memorandum on "Why People Start To Smoke." The memorandum observes that once people start to smoke, one of the reasons they will continue to smoke is that cigarettes serve as "*a narcotic, tranquilizer, or sedative.*"[421]
- In 1978, the authors of Philip Morris' 5-year plan for research and development stated that "*nicotine may be the physiologically active component of smoke having the greatest consequence to the consumer.*"[422]
- In 1980, Philip Morris researcher Jim Charles, who subsequently became vice president for research and development, wrote the then vice president for research and development, Robert Seligman, that:

> *Nicotine is a powerful pharmacological agent with multiple sites of action and may be the most important component of cigarette smoke. Nicotine and an understanding of its properties are important to the continued well being of our cigarette business since this alkaloid has been cited often as "the reason for smoking."*. . . Nicotine is known to have effects on the central and

[420] Philip Morris Research Center, *Behavioral Research Annual Report, Part II* (Nov. 1, 1974) (approved by Osdene TS), in 141 Cong. Rec. H7658, H7660 (daily ed. Jul. 25, 1995). *See* AR (Vol. 14 Ref. 175a).

[421] Udow A (Philip Morris Inc.), *Why People Start to Smoke* (Jun. 2, 1976), in 141 Cong. Rec. H7664 (daily ed. Jul. 25, 1995) (emphasis added). *See* AR (Vol. 14 Ref. 175a).

[422] Philip Morris Inc., *Research and Development Five-Year Plan, 1979-1983* (Sep. 1978), in 141 Cong. Rec. H7668 (daily ed. Jul. 25, 1995) (emphasis added). *See* AR (Vol. 14 Ref. 175a).

> peripheral nervous system as well as influencing memory, learning, pain perception, response to stress and level of arousal.[423]

A statement that the Agency received from a former Philip Morris research director, William Farone, expresses similar views. Farone was the director of applied research at Philip Morris from 1976-1984, during which period he supervised five divisions and 150 employees. According to Farone's statement:

> It is well recognized within the cigarette industry that *there is one principal reason why people smoke—to experience the effects of nicotine*, a known pharmacologically active constituent in tobacco. . . .
>
> . . . .
>
> *The strongly held conviction of most industry scientists and product developers was that nicotine was the primary reason why people smoked.*[424]

The administrative record contains many additional statements by Philip Morris researchers and officials acknowledging the significant pharmacological effects of nicotine and their importance to the smoker. *See, e.g.,* 60 FR 41584–41603, 41621–41667. Collectively, these statements show that Philip Morris' senior scientists and officials have known for decades that cigarettes function as a drug delivery system, providing the pharmacological effects of nicotine to consumers who smoke cigarettes for the primary purpose of obtaining these effects.

ii. Research into Nicotine Pharmacology. The foregoing views of Philip Morris' top research scientists and officials were based on extensive in-house research on

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[423] Charles JL (Philip Morris Inc.), *Nicotine Receptor Program-University of Rochester* (Mar. 18, 1980), in 141 Cong. Rec. H7680 (daily ed. Jul. 25, 1995) (emphasis added). *See* AR (Vol. 14 Ref. 175a).

[424] Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 1,6 (emphasis added). *See* AR (Vol. 638 Ref. 2).